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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

MONSHIPOURI, M

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

05/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.  
**09/593,828**

Applicant(s)  
**Rosen et al.**

Examiner  
**Maryam Monshipouri**

Art Unit  
**1652**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) ☐ Responsive to communication(s) filed on \_\_\_\_\_

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4) ☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☒ Claims 1-29 are subject to restriction and/or election requirements.

### Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4 , drawn to a glycosyl sulfotransferase and its fragments, classified in class 435, subclass 193.
- II. Claims 5-12, drawn to nucleic acid sequences encoding said sulfotransferase, expression cassettes and cells comprising said sequences and methods of expressing said sequences, classified in class 435, subclass 193.
- III. Claims 13-15, drawn to antibodies which specifically bind said transferase, classified in class 530, subclass 387.1.
- IV. Claims 16-22, drawn to a method of inhibiting a binding event between a selectin and its ligand comprising using an agent that modulates the sulfation activity of said transferase, classified in class 435, subclass 15.
- V. Claims 23-24, drawn to a method of modulating a symptom in a mammal diseased with a condition related with a selectin mediated binding event comprising administering a modulator of sulfation activity, classified in class 514, subclass 789.
- VI. Claims 25-27, drawn to a method of diagnosing a disease comprising determining the amount of glycosyl transferase or a nucleic acid related hereto as analyte, classified in class 435, subclass 15.
- VII. Claim 29, drawn to a non-human transgenic animal comprising a gene encoding said sulfotransferase, classified in class 800, subclass 13.

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The inventions are distinct, each from the other because of the following reasons:

The polypeptides of Group I, the DNA of Group II, the antibodies of Group III and the transgenic animals of Group VII are each patentably distinct from the other because each product has a different chemical structure and function.

The polypeptides of Group I are unrelated to the methods of Groups IV and V because said products are neither made nor used by said methods.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the sulfotransferase of Group I may be used in antibody preparation which is an entirely different method than that of Group VI.

The DNA of Group II and the antibodies of Group III are each unrelated to any of the methods of Group IV-VI because said products are neither made nor used by said methods.

The methods of Groups IV-VI are each patentably distinct from the other because each method has different steps and different end-points.

The transgenic animal of Group VI is unrelated to the methods of Group IV-VI because said product is neither made nor used by said methods.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their separate classification, restriction for examination purposes as indicated is proper.

Claims 1-29 are generic to a plurality of disclosed patentably distinct species comprising GST4alpha, GST-4beta and GST-6. Applicant is required under 35 U.S.C. 121 to **elect a single disclosed species**, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Ms. Paula A. Borden on 3/8/01 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308-1083. The examiner can normally be reached between 8:00 a.m. and 5:00 p.m. daily except for Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

*M. Monshipouri*

Maryam Monshipouri, Ph.D.

Patent Examiner